REMARKS

Claims 1-26 are pending in the present application. Claims 7-9 and 20-22 were previously withdrawn from consideration. By virtue of this response, claims 1, 7, 14, 20 and 21 have been amended and new claims 27-41 have been added. Accordingly, claims 1-6, 10-19, and 23-41 are currently under consideration. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented.

Amendments to the Specification

The specification has been amended at paragraphs [0011], [0012], [0015], [0020], [0077], [0113], [0130], [0131], [0177], [0181], [0185], and [0186] to recite sequence identification numbers and to correct a typographical error in the sequences.

Support for the amendments that clarify the correct polynucleotide sequences of LJP 394, may be found, for example, in paragraph [0177] at pages 63-64. For instance, paragraph [0177] states that "[a] description of the synthesis of the conjugate LJP 394, a tetravalent conjugate, is described in Jones et al. (1995) and in U.S. Patent 5,552,391, which are hereby incorporated by reference." The reference "Jones et al. (1995)" is Jones et al., J. Med. Chem (1995) 38:2138-44, as indicated in paragraph [0013] at page 6 of the specification. Jones et al. (1995) and U.S. Patent No. 5,552,391 disclose the polynucleotide sequences of LJP 394. See, e.g., Figure 6B, Example 7, lines 42-43 of column 76, and line 66 of column 8 to line 1 of column 9 of U.S. Patent No. 5,552,391. Based on these disclosures, one of ordinary skill in the art would have recognized that the correct and intended polynucleotide sequences are the sequences reflected in the amendments to the specification and claims.

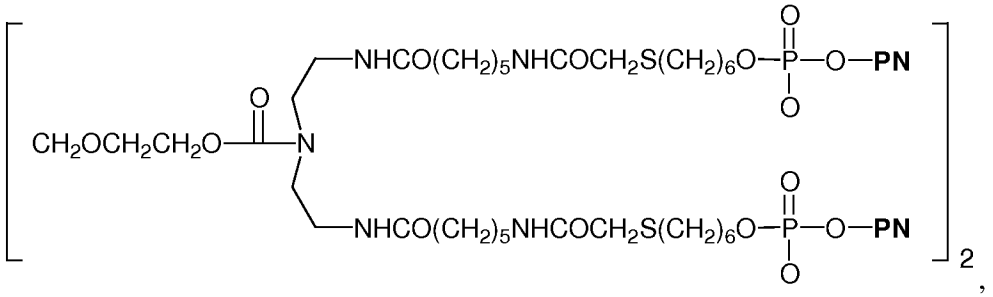
No new matter is added.

Amendments to the Claims

Claims 1 and 14 have been amended and new claims 27-41 have been added.

Claims 1 and 14 have been amended to add a recitation that the sustained reduction of anti-ds-DNA antibody is "for at least about one month." Support for this amendment can be found at paragraph [0011] on page 4 and paragraph [0016] on page 8.

Claims 1 and 14 have been amended to add a recitation "wherein if the dsDNA epitope is administered weekly in the form of a conjugate of the formula



wherein PN is $(CA)_{10}$•$(TG)_{10}$ ((SEQ ID NO:2)•(SEQ ID NO:1)), the administration of the dsDNA epitope comprises administering a dose of about 3 mg/kg or higher of the conjugate to the individual." Support for this amendment can be found at paragraph [0119] beginning on page 45 and at paragraph [0177] beginning on page 63 of the specification. Applicants note that a 200 mg dose for a person of standard weight between 60 and 70 kg is equivalent to about 3 mg/kg.

Support for newly added claims 27 and 28 can be found in the specification, *inter alia*, at paragraph [0177] on page 64. Sequence identifiers have been added to the $(CA)_{10}$•$(TG)_{10}$ sequence claimed in claim 27.

Support for newly added claims 29-40 can be found in the specification, *inter alia*, at paragraph [0119] beginning on page 45.

Support for newly added claim 41 can be found in the specification, *inter alia*, at paragraph [0119] on page 46.

With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and, moreover, have not acquiesced to any rejections and/or objections made by the Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part, and/or divisional applications.

Claim Rejections under 35 U.S.C. §112 Second Paragraph

Claims 3, 5, 6, 16, 18 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner contends that, with respect to the phrase "wherein the double stranded DNA epitopes are polynucleotides," it is unclear what the polynucleotide is intended to limit (page 2, Office Action).

In response, Applicants point to the definition of "double-stranded DNA epitope" at paragraph [0046] at page 18 of the specification. From this definition, it is clear that the term "double-stranded DNA epitope" encompasses polynucleotides but is not limited to only polynucleotides.

In view of the foregoing, Applicants respectfully request that the indefiniteness rejection be withdrawn.

Claim Rejections under 35 U.S.C. §112 First Paragraph

Claims 1-6, 10-19 and 23-26 are rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that the specification, while being enabling for a method of treating systemic lupus erythematosus (SLE) and reducing renal flare in a subpopulation of human individuals characterized by having high affinity IgG antibodies to LJP 394, comprising administering to said individuals an effective amount of LJP 394 to reduce the levels of anti-dsDNA antibodies, allegedly does not reasonably provide enablement for a method of treating SLE and reducing the risk of renal flare in any human individual following the administration of LJP 394, resulting in an indefinitely sustained reduction in anti-dsDNA antibody.

Applicants respectfully traverse this rejection. However, in the interest of expediting prosecution, the amendments have been made to claims 1 and 14 that recite the sustained reduction of anti-dsDNA antibody for at least about one month. Applicants also note that claims 1 and 14 have been amended to recite administering a dose of about 3 mg/kg or higher of the conjugate.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw this rejection.

Claim Rejections under 35 U.S.C. §102

Claims 1-6, 10-19 and 23-26 are rejected under 35 U.S.C. 102(b) as being allegedly anticipated by Wallace (Exp. Opin. Invest. Drugs 10:111-117; 2001; or record). The Examiner contends that Wallace teaches the results show clinical benefits in patients with high affinity IgG antibodies to LJP 394. The Examiner concedes that Wallace does not present results showing a sustained reduction of anti-dsDNA antibody in the individual but contends that this limitation is an inherent property of the dose and treatment regimen of SLE patients with LJP 394.

Applicants respectfully traverse this rejection, however, in view of the amendments that have been made to claims 1 and 14, the rejection with the Wallace reference under 35 USC 102(b) is rendered moot. For a claim to be anticipated by a reference, that reference must teach each and every element of the claim. MPEP 2131. Applicants have amended the claims to recite a particular dose ("3 mg/kg or higher") is administered if the dsDNA epitope that is administered is in the form of LJP 394.

In view of the foregoing, Applicants respectfully request that the Examiner withdraw this rejection.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 252312008000. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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